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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,566	06/25/2003	Valerie Wittamer	9409/2045B	7945

29933 7590 09/19/2007

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
09/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/603,566	WITTAMER ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9,10,20 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,10,20 and 22* is/are rejected.

7)☒ Claim(s) *5,6 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence alignment*.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/02/2007 has been entered.

On further consideration, Claims 6 (invention group II), 7 and 9 (Invention group III) are rejoined with Invention group I in view of the elected species of SEQ ID NO: 61. Thus, claims 1-7, 9, 10, 20, and 22 are pending and under consideration.

Withdrawn Objections and/or Rejections

The rejections of claims 1-5 and 20 under 35 U.S.C. 102(b) as being anticipated by Nagpal et al. (*J. Invest. Dermatol.* 109: 91-95, 1997) and the rejection of claims 1-5, 10, 20, and 22 under 35 U.S.C. 102(e) as being anticipated by Lal et al. (US Patent Application Publication No. 2005/0084936 A1, publication date: April 21, 2005; 102 (e) date: December 31, 1997) are withdrawn in view of amended claim 1.

Objection to the Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because not all the amino acid sequences present in the specification (see, e.g., page 84, line 2), claim 1 (line 4), and drawings (see, e.g., Fig. 20 (a) and Fig. 22 B) have been identified with a SEQ ID NO.

All the amino acid sequences appearing in the specification and drawings must be identified by a sequence identifier in accordance with 37 C.F.R. 1.821(d). Sequence identifiers for sequence appearing in the drawings may appear in the Brief Description of the Drawings. Applicants must provide appropriate amendments to the specification claim or drawings inserting the required identifiers. If the amendments are extensive then a substitute specification may be required.

It is suggested that the amino acid sequence "KALPRS" recited in claim 1 can be identified, for example, as "amino acids 158 to 163 of SEQ ID NO: 8".

Claim Rejections—35 USC § 112, 1st paragraph

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 7 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 7 is drawn to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 73. The specification discloses that the 163 amino acid full-length preprochemerin polypeptide is first produced in a cell as inactive form (Figure 6). This inactive form of Chmerin is converted into the active form of Chmerin (137 amino acids) by the following two steps: a) removing 20 amino acids at N-terminus (this form is called prochemerin, 143 amino acids, Figure 8); and removing 6 amino acids at C-terminus (137 amino acids, Figure 9). From this disclosure, it is clear that the Chemerin polypeptide of SEQ ID NO: 73 is unlikely active in binding the ChemerinR polypeptide of SEQ ID NO: 2. The disclosure provides no guidance and/or working examples on using the Chemerin polypeptide of SEQ ID NO: 73 in a binding assay. The prior art teaches preprochemerin sequences (see the references recited in the specification at page 27).

However, the prior art does not teach the binding between the ChemerinR polypeptide of SEQ ID NO: 2 and the Chemerin polypeptide of SEQ ID NO: 73.

Claim 22 is drawn to a therapeutic composition comprising the polypeptide in any one of the claims 1-10. The term "therapeutic" literally means treatment. However, there is no evidence on the record showing that the polypeptide comprising SEQ ID NO: 94, SEQ ID NO: 92 or SEQ ID NO: 61 can be used to treat a specific disease. Thus, the claimed pharmaceutical composition is not enabled.

Accordingly, the claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

(iii). Claims 1-4, 10, and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising the amino acid sequence of SEQ ID NO: 61, does not reasonably provide enablement for a genus of polypeptides comprising SEQ ID NO: 92, 93 or 94. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv)

the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 1 is drawn to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 94, claims 2 and 3 are drawn to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 92, whereas claim 4 is drawn to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 93, wherein the polypeptide lacks amino acids 158 to 163 of SEQ ID NO: 8 and binds specifically to a chemerinR polypeptide. Each claim is broad and compasses a huge genus of polypeptides. The specification discloses that the 163 amino acid full-length preprochemerin polypeptide is first produced in a cell as inactive form (Figure 6). This inactive form of Chmerin is converted into the active form of Chmerin (137 amino acids) by the following two steps: a) removing 20 amino acids at N-terminus (this form is called prochemerin, 143 amino acids, Figure 8); and removing 6 amino acids at C-terminus (137 amino acids, Figure 9).

The specification also discloses the EC50 value of various truncated Chemerin peptides (Examples 15-17, Table 2). These results indicated that only the last 9 amino acids of Chemerin (SEQ ID NO: 61) are necessary for high affinity receptor activation (Example 16 and Table 2). From this disclosure, it is clear that the amino acid sequence of SEQ ID NO: 61 is necessary for a Chemerin polypeptide to specifically bind to a ChemerinR

polypeptide. However, the disclosure does not provide sufficient guidance and/or working examples to teach that the genus of chemerin polypeptides recited in SEQ ID NO: 94, 93, or 92 bind specifically to a ChemerinR polypeptide. While teaching preprochemerin sequences (see the references recited in the specification at page 27), the prior art does not teach the binding of the genus of Chemerin polypeptides represented by SEQ ID NO: 92, 93, or 94 to a ChemerinR polypeptide, such as the polypeptide of SEQ ID NO: 2. Furthermore, since the binding between two polypeptide can only be determined experimentally as illustrated by the instant disclosure (Examples 15-17), it is unpredictable whether a Chemerin polypeptide of SEQ ID NO: 94, 93, or 92 binds specifically to a ChemerinR polypeptide, such as the polypeptide of SEQ ID NO: 2.

Finally, claim 1 recites a functional limitation "wherein the polypeptide binds specifically to a ChemerinR polypeptide". The specification defines "chemerinR polypeptide" as "a polypeptide having two essential properties: 1) a ChemerinR polypeptide has at least 70% amino acid identity, and preferably 80%, 90%, 95% or higher, including 100% amino acid identity to SEQ ID NO: 2, and 2) a ChemerinR polypeptide has ChemerinR activity, i.e., the polypeptide binds to a Chemerin polypeptide or a functional fragment thereof". However, the instant specification merely disclose the ChemerinR polypeptide of SEQ ID NO: 2 and its binding to various Chemerin polypeptides.

Accordingly, while being enabling for an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 61, the specification does not reasonably provide enablement

for the genus of polypeptides represented by SEQ ID NO: 94, 93, or 92. Thus, it would require undue experimentation for one skilled in the art to use the claimed invention commensurate in scope with the claims.

Claim Rejections under 35 U.S.C.§102(b)

(i). The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(ii). Claims 1-3, 10, and 20 are rejected under 35 U.S.C. 102(b) as being unpatentable over Williams et al. (US Patent No. 5,948,664, Sep. 7, 1999).

Williams et al. teach an isolated polypeptide (SEQ ID NO: 17) that comprises the amino acid sequence of SEQ ID NO: 92 of the present invention (see attached sequence alignment), a composition comprising the polypeptide (column 20, the 2nd paragraph), and a labeled polypeptide with a radioisotope (column 10, lines 60-63), meeting the limitations of claims 1-3, 10, and 20.

(iii). Claims 1-3, 10, and 20 are rejected under 35 U.S.C. 102(e) as being unpatentable over Dumas Milne Edwards et al. (US Patent No. 6,822,072 B1, Nov. 23, 2004; 102 (e) date: Dec. 21, 1999).

Dumas Milne Edwards et al. teach an isolated polypeptide (SEQ ID NO: 1503) that comprises the amino acid sequence of SEQ ID NO: 92 of the present invention (see attached sequence alignment), a composition comprising the polypeptide (column 83, lines 37-43), and a polypeptide labeled with an enzyme, such as green fluorescent protein or β-galactosidase (column 105, lines 59-61), meeting the limitations of claims 1-3, 10, and 20.

Claim Objections

Claims 1-4, 10, 20, and 22 are objected to because of the following informalities: (1). claims 1-4, 10, 20, and 22 recite non-elected species; and (ii). claim 2 is essentially a duplicate of claim 3. Appropriate correction is required.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Primary Examiner
September 12, 2007

RUIXIANG LI, PH.D.
PRIMARY EXAMINER

```
RESULT 8
US-08-609-049A-17
; Sequence 17, Application US/08609049A
; Patent No. 5948664
;  GENERAL INFORMATION:
;    APPLICANT:  Williams, Lewis T.
;    APPLICANT:  Molz, Lisa
;    APPLICANT:  Chen, Yen-Wen
;    TITLE OF INVENTION:  No. 5948664el PI 3-Kinase Polypeptides
;    NUMBER OF SEQUENCES:  32
;    CORRESPONDENCE ADDRESS:
;      ADDRESSEE:  Townsend and Townsend and Crew LLP
;      STREET:  Two Embarcadero Center, 8th Floor
;      CITY:  San Francisco
;      STATE:  California
;      COUNTRY:  USA
;      ZIP:  94111-3834
;    COMPUTER READABLE FORM:
;      MEDIUM TYPE:  Floppy disk
;      COMPUTER:  IBM PC compatible
;      OPERATING SYSTEM:  PC-DOS/MS-DOS
;      SOFTWARE:  PatentIn Release #1.0, Version #1.25
;    CURRENT APPLICATION DATA:
;      APPLICATION NUMBER:  US/08/609,049A
;      FILING DATE:  29-FEB-1996
;      CLASSIFICATION:  435
;    ATTORNEY/AGENT INFORMATION:
;      NAME:  Dow, Karen B.
;      REGISTRATION NUMBER:  29,684
;      REFERENCE/DOCKET NUMBER:  2307K-063700US
;    TELECOMMUNICATION INFORMATION:
;      TELEPHONE:  415-326-2400
;      TELEFAX:  415-326-2422
;  INFORMATION FOR SEQ ID NO:  17:
;    SEQUENCE CHARACTERISTICS:
;      LENGTH:  138 amino acids
;      TYPE:  amino acid
;      STRANDEDNESS:  single
;      TOPOLOGY:  linear
;    MOLECULE TYPE:  peptide
US-08-609-049A-17

  Query Match             76.7%;  Score 23;  DB 1;  Length 138;
  Best Local Similarity   50.0%;  Pred. No. 2.8e+02;
  Matches    4;  Conservative    0;  Mismatches    4;  Indels    0;  Gaps    0;

Qy          1 YFXXXFXF 8
              ||   | |
Db         76 YFNESFSF 83


US-09-471-276-1503
; Sequence 1503, Application US/09471276
; Patent No. 6822072
; GENERAL INFORMATION:
;  APPLICANT: Dumas Milne Edwards, J.B.
;  APPLICANT: Duclert A.
;  APPLICANT: Giordano, J.Y.
;  TITLE OF INVENTION: Expressed Sequence Tags and Encoded Human Proteins.
; Patent No. 6822072
;  FILE REFERENCE: GENSET.025CP1
;  CURRENT APPLICATION NUMBER: US/09/471,276
```

; CURRENT FILING DATE: 1999-12-21
; EARLIER APPLICATION NUMBER: 09/057,719
; EARLIER FILING DATE: 1998-04-09
; EARLIER APPLICATION NUMBER: 09/069,047
; EARLIER FILING DATE: 1998-04-28
; EARLIER APPLICATION NUMBER: PCT/IB99/00712
; EARLIER FILING DATE: 1999-04-09
; NUMBER OF SEQ ID NOS: 1622
; SOFTWARE: Patent.pm
; SEQ ID NO 1503
;   LENGTH: 50
;   TYPE: PRT
;   ORGANISM: Homo sapiens
;   FEATURE:
;   NAME/KEY: SIGNAL
;   LOCATION: -44..-1
US-09-471-276-1503

  Query Match   76.7%; Score 23; DB 2; Length 50;
  Best Local Similarity   50.0%; Pred. No. 1.2e+02;
  Matches   4; Conservative   0; Mismatches   4; Indels   0; Gaps   0;

Qy   1 YFXXXFXF 8
              || | |
Db   26 YFYSNFSF 33